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10/574,252	11/28/2006	David John Chapman-Jones	51407/P029US/10605267	9077

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EXAMINER	
PATEL, SHEFALI DILIP	
ART UNIT	**PAPER NUMBER**
3767	

NOTIFICATION DATE	DELIVERY MODE
01/07/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

doipdocket@fulbright.com

Office Action Summary	Application No.	Applicant(s)	
	10/574,252	CHAPMAN-JONES, DAVID JOHN	
	Examiner	Art Unit	
	SHEFALI D. PATEL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26,29-39 and 48* is/are pending in the application.

4a) Of the above claim(s) *34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26,29-33,35-39 and 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/12/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgments

1. In the reply, filed on November 12, 2010, Applicant amended claims 29 and 37.

2. In the non-final rejection of July 14, 2010, Examiner objected to claim 37 for a minor informality. Applicant amended claim 37. Objection is withdrawn.

3. Currently, claims 26, 29-33, 35-39, and 48 are under examination.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 26, 29, 35, 36, and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Lin-Hendel (US 7,167,752).

In regards to claim 29, Lin-Hendel teaches a device (Figure 7) for treating tissue, the device comprising:

a. a dressing (conductive gel-pads) for applying to a treatment area of said tissue (column 5, lines 4-8)

b. a pair of electrodes (coil shaped electrodes) affixed to a treatment surface of the dressing (column 5, lines 4-8)

c. a control unit (clock [76], processor [77], data memory [78], and program memory [79]) for passing alternating current to the treatment area via the electrodes and for constantly varying the value of the amplitude of the alternating current to electrically stimulate and repair said tissue (column 4, lines 54-64)(Figures 8A-8B)

In regards to claim 26, Lin-Hendel teaches that the control unit and the dressing are integrated with each other (Figure 7).

In regards to claim 35, Lin-Hendel teaches that the control unit comprises a housing (clinical device [70]) and electronic circuitry [76][77][78][79][701] in the housing connected to the pair of electrodes (Figure 7)

In regards to claim 36, Lin-Hendel teaches that the electronic circuitry comprises memory [79] storing at least one program for determining the amplitude, frequency, and waveform of alternating current supplied to the electrodes (column 4, lines 54-64)(column 13, lines 41-42).

In regards to claim 48, Lin-Hendel teaches that the control unit is also for constantly varying the frequency of the alternating current (column 4, lines 54-64)(Figure 8B).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin-Hendel, as applied to claim 29 above.

In regards to claim 30, Lin-Hendel does not teach that the alternating current is varied between 50 and 500 microamps, as Lin-Hendel teaches that the alternating current is varied between a few mAmps to up to 200 mAmps (column 6, lines 57-58). But it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the alternating current to be varied between 50 and 500 microamps, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

In regards to claim 31, Lin-Hendel does not teach that the frequency of the alternating current is varied between 10 and 900 hertz, since Lin-Hendel teaches that the frequency is varied between 0.5 and 200 hertz (column 6, lines 50-52). But it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the frequency to be varied between 10 and 900 hertz, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

In regards to claim 32, Lin-Hendel is silent about whether the time period between each variation of amplitude is 0.1 s. However, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the time period between each variation of amplitude to be 0.1 s, since it has been held that discovering the optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

8. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lin-Hendel, as applied to claim 29 above, and further in view of Fleming (US 5,891,182).

In regards to claim 33, Lin-Hendel is silent about whether the alternating current has a ramp waveform. Fleming teaches a device for treating tissue, wherein an alternating current has a ramp waveform. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the alternating current, of the device of Lin-Hendel, to have a ramp waveform, as taught by Fleming, as the ramp up or soft start of the current applied to the patient will allow the patient to become quickly acclimated to the application of the current through the electrodes without undue surprise to the patient (column 7, lines 42-45).

9. Claims 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin-Hendel, as applied to claim 36 above, and further in view of Fischell et al (US 2002/0099412).

In regards to claims 37 and 38, Lin-Hendel teaches that the control unit comprises an i/o port (input [73] and output [74]) connected to the electronic circuitry; however, Lin-Hendel is silent about whether an external device, such as a wireless transceiver, can connect to the control unit via the i/o port and update the memory and control operation of the control unit. Fischell et al teaches a device comprising an i/o port connected to the electronic circuitry, such that an external device can wirelessly connect to the control unit via the i/o port and update the memory and control operation of the control unit (paragraphs [0170] [0171]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the i/o port, of the device of Lin-Hendel, to connect to an external device such as a wireless transceiver,

as taught by Fischell et al, as such will allow the i/o port to wirelessly receive physician commands from the physician's external equipment and will read and send back disorder event related data previously stored in the memory back to the physician's external equipment (paragraph [0170] [0171]).

10. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lin-Hendel, as applied to claim 35 above, and further in view of Claude (US 4,982,742).

In regards to claim 39, Lin-Hendel does not teach a removable tab including a metallic strip that connects the electrodes and only allows current to pass once the tab is removed. Claude teaches a device (Figures 1-5) wherein a removable tab (pull away tab [52]) is electro-mechanically connected between a power source [50] and a ground point on the control unit [28]. When the tab [52] is intact, the power source [50] is connected to ground point and energization of the control unit [28] does not occur. Once the tab is removed, the electrical connection between the power source [50] to ground point is broken, and as result, the power source [50] drives the control unit [28] to generate current toward the electrodes (column 3, lines 37-45). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the device, of Lin-Hendel, with a removable tab, as taught by Claude, as the removable tab will provide a means for controlling the energization of the control unit to allow for or prevent delivery of current to the electrodes (column 3, lines 37-45). Further, Claude is silent about whether the removable tab [52] is metallic. But it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the removable tab to include a metallic material, since it has been held to be within the general skill

of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416. Also, it is common knowledge to those of ordinary skill in the art to choose a material that has sufficient conductibility, such as a metal, in electrical energy applications.

Response to Amendment

11. The amendment to the claims filed on November 12, 2010, does not comply with the requirements of 37 CFR 1.121(c) because claim 34 has been provided with the incorrect status identifier (Previously presented). Originally, claim 34 was not examined as it was withdrawn, and Applicant has not stated in the reply why claim 34 is to be not withdrawn and examined. Hence, it is Examiner's understanding that claim 34 is to remain withdrawn and therefore should be provided with the status identifier (Withdrawn). Amendments to the claims filed on or after July 30, 2003 must comply with 37 CFR 1.121(c) which states:

(c) Claims. Amendments to a claim must be made by rewriting the entire claim with all changes (e.g., additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. **The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).**

(1) Claim listing. All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of "canceled" or "not entered" may be aggregated into one statement (e.g., Claims 1–5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the claims shall not contain any other part of the amendment.

(2) When claim text with markings is required. All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of

"currently amended," and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of "currently amended," or "withdrawn" if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as "withdrawn—currently amended."

(3) When claim text in clean version is required. The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, i.e., without any markings in the presentation of text. The presentation of a clean version of any claim having the status of "original," "withdrawn" or "previously presented" will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of "withdrawn" or "previously presented." Any claim added by amendment must be indicated with the status of "new" and presented in clean version, i.e., without any underlining.

(4) When claim text shall not be presented; canceling a claim.

(i) No claim text shall be presented for any claim in the claim listing with the status of "canceled" or "not entered."

(ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying the status of a claim in the claim listing as "canceled" will constitute an instruction to cancel the claim.

(5) Reinstatement of previously canceled claim. A claim which was previously canceled may be reinstated only by adding the claim as a "new" claim with a new claim number.

Since the reply filed on November 12, 2010, appears to be bona fide, applicant is given a TIME PERIOD of **ONE (1) MONTH** or **THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to submit an amendment in compliance with 37 CFR 1.121 in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

Response to Arguments

12. Applicant's arguments with respect to claims 26, 29-33, 35-39, and 48 have been considered but are moot in view of the new ground(s) of rejection, based on the insertion of subject matter not previously presented in the claims into independent claim 29.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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